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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,686	12/10/2003	Yaron Ilan	59046.000043	9035

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HUNTON & WILLIAMS LLP
INTELLECTUAL PROPERTY DEPARTMENT
1900 K STREET, N.W.
SUITE 1200
WASHINGTON, DC 20006-1109

EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/733,686	ILAN ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37,40-42,45-49,63 and 64* is/are pending in the application.

4a) Of the above claim(s) *46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37, 40-42, 45, 47-49 and 63-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/15/2007 has been entered.

Status of Claims

2. Claims 1-36, 38-39, 43-44 and 50-62 are cancelled. Claims 37, 40-42, 45-49 and 63-64 are pending. Claim 46 is withdrawn for being directed to a non-elected invention, which is HCV. Claims 37, 40-42, 45, 47-49 and 63-64 are under examination.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 37, 40-42, 45, 47-49 and 63-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In response to the rejection, Applicant argues that the claims are fully supported in the specification as originally filed and a person of skill in the art would recognize that Applicants were in full possession of the claimed invention.

Applicant's submission has been considered, however, it is not found persuasive. The written description requirement requires that the claimed invention be described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the invention was filed, had possession of the claimed invention. In the instant case, all that the specification has described is an association study between metabolites and HCV, as obtained from HCV infected subjects who are diagnosed with Gaucher's disease or is free of Gaucher's disease. This study associates metabolite levels with an immune component, and how they differ between the two test populations. However, such is not sufficient to reasonably convey to the skilled artisan in the relevant art that Applicant had possession of the claimed invention. All that the description provided in the specification is reasonably convey to the skilled artisan that Applicant is in possession of an association study, rather than a method of treating HCV infection. It should be noted that the written description requirement is not limited to whether the text recited in the claims are present in the specification, the requirement requires the specification to provide a description of the claimed invention in such a way to reasonably convey to one skilled in the relevant art that Applicant had possession of the claimed invention. In this case, such is not found. In the absence of a description that would reasonably convey to one skilled in the art that glycolipids

treats HCV, then the claimed invention fails to satisfy the written description requirement.

In response to the written description rejection, Applicant alleges that the Office is clinging to the incorrect notion that structural is required for an adequate written description. Applicant also submits that Applicant has provided adequate written description for the glycolipids that is useful in treating HCV. To support this submission, Applicant cited lines 1-9, page 7 and pages 13-15.

This allegation has been noted, however, it is not found persuasive. As noted previously, the issue here is whether Applicant has disclosed the structural chemical formulas of glycolipids. The issue is that Applicant has not provided sufficient description of the claimed invention that would reasonably convey to the skilled artisan that Applicant is in possession of a glycolipid that treats HCV. While examples are not necessary to support the adequacy of a written description, the written description standard may still be met when actual reduction to practice of the claimed invention is absent, and that there is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure; however, it should be noted that to satisfy the written description requirement, Applicant must describe the claimed invention in a way that would reasonably convey to one of skilled in the relevant art that Applicant is in possession of the claimed invention. In this case, Applicant has not provided a description that is adequate to reasonably convey to the skill artisan that Applicant is in possession of a glycolipid that treats HCV. As mentioned above, the issue is not whether Applicant has provided adequate written

description of glycolipids, it's whether Applicant has provided adequate written description of glycolipids that treats HCV.

Regarding Applicant's assertion that Applicant has provided adequate written description for the glycolipids that is useful in treating HCV, the Office has reviewed the entire specification, and disagrees with Applicant's assertion. The entire specification does not contain any evidence demonstrating or showing that glycolipids, including any of the glycolipids identified in the specification or known in the art, are useful in treating HCV infection. All that is found in the specification is a suggestion of the use of glycolipids to treat HCV through an association study that notes that the immune profile of HCV infected subjects varies if the subjects are diagnosed with Gaucher's disease. Through this association, Applicant suggests the administration of glycolipids to modulate the immune profiles to treat HCV. Yet, Applicant has not demonstrated or provided any guidance as to which component of the immune profile must be modulated to treat HCV infection. Nor has Applicant provided any evidence demonstrating that glycolipids are capable of providing the immune profile necessary to treat HCV infection. Furthermore, following Applicant's reasoning, it should be noted that HCV infection in subjects diagnosed with Gaucher's disease would also clear itself since the subject all ready has a buildup of glycolipids. However, this scenario is not found or noted in Applicant's disclosure. Applicant's disclosure clearly notes that subjects diagnosed with Gaucher's disease are also infected with HCV infection.

As Applicant has indicated in Applicant's submission, the specification describes how glycolipids can be used to treat various diseases. [with emphasis] The

specification has only provided a description that suggests the use of glycolipids to treat various diseases, however, nothing else is present in the specification to further substantiate or advance this suggestion. In the absence of additional evidence demonstrating that glycolipids treats various diseases, one skilled in the relevant art would not reasonably conclude that Applicant is in possession of the claimed invention. The same is also noted regarding the use of glycolipids to treat small cell carcinoma of the lung. Again, all that is present in the specification is a suggestion of administering glycolipids to treat diseases that is not substantiated by any evidence that would reasonably convey to one skilled in the art that Applicant is in possession of the claimed invention.

In the instant case, the claims are directed to a process for treating a HCV infection in a subject with the administration of a glycolipid to the subject.

The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under Vas- Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is

whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." Ralston Purina Co. v. Far-Mar-Co., Inc., 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting In re Kaslow, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)). Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). **Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention**. See, e.g., Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); Regents of the University of California v. Eli Lilly, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997); Amgen, Inc. v. Chugai Pharmaceutical, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics

sufficiently distinguish it"). See MPEP § 2163 for examination guidelines pertaining to the written description requirement.

The specification does not contain a description of the claimed invention by actual reduction to practice. The specification does not contain any working examples demonstrating or evidencing the administration of glycolipids treats HCV infection. Nor does the specification contain drawings demonstrating that the administration of glycolipids treats HCV. The specification fails to provide a description of the claimed invention showing that the claimed invention is complete, ready for patenting. That is, there does not exist any evidence that the administration of glycolipids treats HCV provided in the specification. While the Office acknowledges that Applicant has identify the use of glycolipids, and that one of ordinary skill in the art would readily be able to ascertain the structural chemical formulas of glycolipids, however, the issues remains that Applicant has failed to provide a description of the glycolipids that treats HCV. As noted above, the claimed invention is directed at the administration of glycolipids to treat HCV. In the instant case, the Office credits the efforts made by Applicant with their observation that the immune profiles of HCV infected subjects varies if they are also diagnosed with Gaucher's disease, where there is a buildup of glucosylcerebroside (glycolipid) due to the decreased capacity for breakdown of this product. However, this observation is not sufficient to demonstrate or convey to the skilled artisan that Applicant is in possession of a method of treating HCV with the administration of glycolipids. It should be noted that all Applicant has provided is an analysis in the difference in immune profiles for different treatment population. However, the analysis is

merely an association study, wherein HCV is the common denominator. It is through this association study that Applicant suggests the administration of glycolipids to treat HCV. Specifically, the specification suggests taking advantage of this difference in immune profile, which is modulated by the presence or absence of a buildup of glycolipids, to achieve one change in an immune component in a subject infected with HCV with the administration of the glycolipids to treat the subject of HCV infection. [Paragraph bridging pages 12-13, in particular.] However, it should be noted that Applicant has not performed any research or investigation to determine which immune component has to be changed via the administration of glycolipids to treat HCV. Nor has Applicant performed any study showing that the administration of glycolipids is indeed effective in treating HCV. In the instant case, the specification is devoid of any evidence relating to the effective use of glycolipids to treat HCV infection. Applicant has not reasonably conveyed to the skilled artisan that Applicant is in possession of the claimed invention; at the time it was filed, via any distinguishing characteristics. Applicant has not even characterized the effect of glycolipids in subjects that are infected with HCV. All Applicant has provided are immune profiles that associate HCV with Gaucher's disease. Beyond that association, Applicant has not done any additional research to reasonably convey to the skilled artisan that glycolipids are effective in treating HCV infection. Furthermore, in accordance with Applicant's reasoning, HCV infection in subjects diagnosed with Gaucher's disease, which have a vast reservoir of glycolipids due to the decreased capacity to breakdown this product, would have readily resolved itself; however, it should be noted that this scenario is not readily found in

Applicant's specification. Overall, the instant specification does not reasonably convey to the artisan that the inventor had possession at that time of the later claimed subject matter. Hence, the claims are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

5. Claims 37, 40-42, 45, 47-49 and 63-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In response to the rejection, Applicant traversed the rejection. Applicant asserted that, contrary to the Office's position, the specification does contain enough guidance as to the type or kind of reagent used in the methods of the claimed invention. Applicant also submits that the specification provides guidance as to the types of disease to which the present invention applies. That is, as Applicant submitted, the specification clearly set forth a protocol for testing the effects of the intermediary metabolite, glycolipids, on the immune profile of patients suffering from HCV infection, which amounts to the adequate guidance without requiring an unreasonable amount of experimentation.

Applicant's submission has been considered, however, it is not found persuasive. The enablement rejection is made on the basis of the Wands factors as a whole, and is not limited to whether specification contains enough guidance as to the type or kind of reagent used in the methods of the claimed invention. The issue is not whether Applicant has identified a reagent or metabolite to administer. The issue is that

Applicant has not provided any guidance pertaining to the administration of the reagent or metabolite to therapeutically treat HCV. All that Applicant has provided in the specification is a suggestion of administering a reagent or metabolite, such as glycolipids, to treat HCV; yet the suggestion is not substantiated by any evidence demonstrating that glycolipids therapeutically treat HCV. What Applicant has is a method of modulating an immune component with the administration of a glycolipid. Such method does not commensurate with a method of treating HCV with the administration of glycolipids nor does it remotely relate to a therapeutic use of glycolipids to treat HCV. In the instant case, Applicant has not provided any guidance relating to the therapeutic use of glycolipids to treat HCV. All that Applicant has provided is the speculative use of glycolipids to modulate an immune component to treat HCV. Yet, Applicant fails to provide any guidance as to which immune component must be modulated, is the modulation an up regulation or down reuglation, how much modulation is necessary, and if glycolipids are capable of providing the necessary modulation.

It is noted that specification discloses experiments that describes the impact of increased metabolite level, glycolipids, on the immune profile of HCV. However, it should be noted that the experiments fall short of demonstrating that glycolipids are therapeutically effective in treating HCV.

Regarding Applicant's assertion that the specification provides guidance as to the types of disease to which the present invention applies, it should be noted that this guidance is distinct from the guidance that would enable the skilled artisan to practice

the claimed invention without an undue burden of experimentation. The guidance provided by Applicant is a suggestion of using glycolipids to treat various diseases, yet, the guidance does not teach or demonstrate that glycolipids are therapeutically effective in treating HCV infection. To enable the claimed invention, the guidance necessary is distinct from the guidance that is provided in the specification. As noted in the preceding paragraphs, all that the specification has provided is guidance on the speculative administration of glycolipids to treat various diseases, because it is found that glycolipids modulate an immune component. In the instant case, as it pertains to the elected invention, Applicant has not even described the immune component that must be modulated with the glycolipids, whether the modulation should be up or down, and the threshold in which the modulation must take place in order to provide HCV treatment in a subject.

Addition, while the specification clearly set forth a protocol for testing the effects of the intermediary metabolite, glycolipids, on the immune profile of patients suffering from HCV infection, as alleged by Applicant, such does not amount to the adequate guidance without requiring an unreasonable amount of experimentation. As noted above, the protocol provided in the specification does not commensurate with the claimed invention. The claimed invention is not a method of testing the effects of glycolipids of immune profile of patients suffering from HCV. The claimed invention is directed at the administration of glycolipids to treat HCV. In the instant case, the protocol directing and evidencing the administration of glycolipids to treat HCV is not provided for in the specification.

Applicant further submits that the absence of working examples does not itself render the invention non-enable.

This submission has been considered, however, it is not found persuasive. The enablement rejection is based on the Wands factors as a whole, rather than whether or not the specification contains any working examples. The presence or absence or working examples is one of the points of discussion used in evaluating whether the claimed invention is enabling by the specification. In the instant case, as noted in the rejection, the specification does not contain any working examples directed at the administration of glycolipids to treat HCV. The specification does not contain any working example relating to the effectiveness of glycolipids in treating HCV. In the absence of the any working examples, the skilled artisan would not readily be able to practice the claimed invention without experimentation. Compounded further by the absence of any guidance or direction directing or evidencing the therapeutic use of glycolipids to treat HCV, the experimentation required of the skilled artisan would be sufficient to be undue experimentation. Affirmation of this burden of undue experimentation on the skilled artisan practicing the claimed invention is further provided by the challenges recognized in the HCV art, such as an absence of good animal models, besides humans and chimpanzees, the ability of HCV to evade effective immune recognition, the high rate of viral persistence, absence of an effective cell culture system for HCV, and the lack of understanding on the role of innate and antigen-nonspecific immune response to HCV, all of which is discussed below. In view of a

nonenabling disclosure, the skilled artisan in the HCV art would not be able to seek any guidance, direction or relief from the HCV art in practicing the claimed invention.

In response to the rejection, Applicant argues that the Office has misapprehend the enablement rejection since it is well established that the test of enablement is not whether any experimentation is necessary but whether if the experimentation is necessary, it is undue.

Applicant's arguments has been considered, however, it is not found persuasive. Contrary to Applicant's assertion, the Office has not misapprehended the enablement requirement. It appears that Applicant is the one that has not fully grasp the enablement requirements and its analysis. In the instant case, as determined in the rejection provided, the experimentation that the skilled artisan would necessarily conduct is undue experimentation because Applicant has not provided a disclosure that would enable the skilled artisan to practice the claimed invention without having to blindly and unduly experiment. All Applicant has provided is an association between glycolipids and its ability to modulate immune components. From this association, Applicant asserts that the administration of glycolipids can be used to modulate an immune component in HCV infected subjects to treat the subject of HCV. Yet, the assertions provided are not substantiated by any evidence demonstrating that glycolipids are therapeutically effective against HCV.

Applicant argues that the specification discloses a class of compounds that can be used with the claimed invention, thus, no blind experimentation would be necessary of the skilled artisan.

This submission has been considered, however, it is not found persuasive. In the instant case, the Office acknowledges that the claims recite the administration of glycolipids. Yet, the Office notes that the specification does not contain any evidence demonstrating that glycolipids are therapeutically effective against HCV. Thus, in the absence of such evidence, it is expected that the skilled artisan would necessarily blindly experiment with glycolipids, immune component in which the glycolipids modulate, and how it therapeutically relates to HCV, and the effective application of the therapeutic discovery.

To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In Genentech *Inc. v. Novo Nordisk* 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997); *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); See also *Amgen Inc. v. Chugai Pharm. Co.,* 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); *In re Fisher* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Further, in *In re Wands* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court stated:

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman* [230 USPQ 546, 547 (Bd Pat App Int 1986)]. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Nature of the invention:

The claimed invention is directed at the treatment of diseases, wherein the elected disease is hepatitis C virus, HCV, with the administration of a glycolipid. As noted by Applicant, the claimed invention relates to the application of glycolipid to regulate and manipulate immune responses, Th1 and Th2 responses, in mammalian subjects to treat mammalian subjects of an infection, particularly wherein the elected infection is hepatitis C virus. [First paragraph, Field of the invention, page 1 of specification.]

Breadth of the claims:

The claims encompass all diseases, wherein the elected disease is hepatitis C virus; all mammalian subjects, and glycolipids.

Presence or absence of working examples and Amount of direction or guidance presented:

The specification does not contain any working examples demonstrating the effective use of glycolipids to treat HCV infection. All that is present in the specification is an association study, which demonstrates that HCV infected subjects have a different immune profile if they are also diagnosed with Gaucher's disease, compared to those that are not diagnosed with Gaucher's disease, where there is a buildup of glucosylcerebroside (glycolipid) due to the decreased capacity for breakdown of this product. Through this association study, Applicant suggests the administration of glycolipids to treat HCV infection by modulating a change in at least one immune component. [Paragraph bridging pages 12-13, in particular.] However, Applicant has not

set forth any guidance or direction relating to the immune component that must be changed or modulated in order to render treatment to HCV infected subjects. What is the immune component that must be modulated or changed? Is it a Th1 or Th2 immune response that must be induced? What kind of Th1 or Th2 induced cytokines must be produced in order to effectively treat HCV? Is this modulation or change directed at increasing or decreasing the activity of this particular immune component? And are glycolipids capable of rendering this change or modulation? In the instant case, beyond the speculative use of glycolipids to treat HCV, Applicant has not provided any additional information or evidence regarding the effective use of glycolipids to treat HCV infection.

State of the prior art:

The hepatitis C virus (HCV) art clearly notes that the role of innate and antigen-nonspecific immune response to HCV has not yet been sufficiently characterized.[1] In the absence of a sufficient characterization of the role of innate and antigen-nonspecific immune responses to HCV, the skilled artisan would not readily be able to practice the claimed invention without an undue burden of experimentation. In the absence of such characterization, the burden is on the skilled artisan to mine the field to determine significance of the innate and antigen-nonspecific in HCV treatment. The art additionally acknowledges several factors that challenge the development of an effective treatment for HCV.[2, 3, 4]

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[1] Knipe DM, Howley PM, eds. Fields virology. 4th ed. Vol. 1. Philadelphia: Lippincott Williams & Wilkins, 2001, 1004-1016 and 1127-1161.
[2] Hahn. Subversion of immune responses by hepatitis C virus: immunomodulatory strategies beyond evasion? Current opinion in Immunology, 2003, Vol. 15, 443-449.

The first factor is the lack of an effective cell culture system for HCV. In the absence of an effective cell culture system for HCV, the skilled artisan would be at an immediate disadvantage when it comes researching the effects of innate or antigen-nonspecific immune responses in HCV treatment. The second challenge is the absence of good animal models for HCV, outside of humans and chimpanzees. In the instant case, the noted disadvantage that the skilled artisan would face in practicing the claimed invention is further compounded by the noted absence of good animal models for HCV. Combined, in the absence of an effective in vitro and in vivo model for conduct HCV research, a prima facie case of undue experimentation and unpredictability is established. The other challenge is the ability of HCV to evade effective immune recognition, including recognition by cytotoxic T lymphocytes (CTL), and shows an extremely high rate of viral persistence. In the instant case, it should be noted that Applicant has not taught the skilled artisan how to deal or address each of the challenges addressed herein. This last point further establishes that the type of experimentation that the skilled artisan would have to perform in practicing the claimed invention is beyond routine experimentation, such as establishing route of administration and treatment dosage amounts. The imposition of experimentations that is beyond routine experimentation would unduly burden the skilled artisan practicing the claimed invention.

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[3] Knipe DM, Howley PM, eds. Fields virology. 4th ed. Vol. 1. Philadelphia: Lippincott Williams & Wilkins, 2001, 1004-1016 and 1127-1161.

[4] De Francesco et al. Challenges and successes in developing new therapies of hepatitis C. Nature, 2005, Vol. 436, 953-960.

Quantity of experimentation necessary:

The skilled artisan cannot rely on the disclosure set forth in the specification to reasonably practice the invention without the burden of undue experimentation. In order for the skilled artisan to successfully practice the claimed invention, the skilled artisan would have to blindly and unduly experiment with glycolipids, each immune component, and determine the relationship among the glycolipids, each immune components and HCV infection.

In all, the skilled artisan practicing the claimed invention would have to bridge the gap between the glycolipids and HCV infection, the gap that should have been substantially filled by Applicant, at the time the invention was filed. In the instant case, the attainment of such knowledge would undeniably be an undoubtedly laborious task that includes both blind and undue experimentations. And the imposition of both blind and undue experimentations would unarguably be an undue burden for the skilled artisan.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F. 2d 1557, 1562, 27 USPQ 2d 1510, 1513 (Fed. Cir. 1993).

Conclusion

6. No claims are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily M. Le/
Patent Examiner
Art Unit 1648

/E.Le/